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DEPARTMENT of HEALTH

ENVIRONMENTAL HEALTH SECTION
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MEMO TO : Medical Use Radioactive Material Licensees in North Dakota

FROM : Terry L. O'Clair, P.E.
Director
Division of Air Quality

TLO

FILE

RE : NRC Regulatory Issue Summary 2006-26: Training and Experience and Grandfather Provisions for Authorized Medical Physicists Under 10 CFR Part 35.

NRC Regulatory Issue Summary 2006-27: Availability of NRC 313A Series of Forms and Guidance for their Completion.

DATE : January 22, 2007

Enclosed are two U.S. Nuclear Regulatory Commission (NRC) Regulatory Issues Summaries (RIS) that relate to medical use of radioactive materials. Please review these RIS's for their applicability to your Radioactive Material Program. North Dakota Radiological Health Rules NDAC 33-10-07.1 is comparable to 10 CFR Part 35.

The U.S. NRC 313A series forms can be found on the Department's Radiation Control Program website: http://www.health.state.nd.us/AQ/RAD/forms/forms.htm.

Please use those forms, when necessary, if they apply to your Radiation Protection Program.

This notice is for you information only, a written response is not required. Please contact the North Dakota Department of Health Radiation Control Program at (701)328-5188 if you have any questions.

CJS:csc
Enc:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

December 7, 2006

NRC REGULATORY ISSUE SUMMARY 2006-26
TRAINING AND EXPERIENCE AND GRANDFATHER PROVISIONS FOR AUTHORIZED MEDICAL PHYSICISTS UNDER 10 CFR PART 35

ADDRESSEES

All NRC medical-use licensees and Radiation Control Program Directors.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the provisions for recognizing and "grandfathering" authorized medical physicists (AMPs) under 10 CFR 35.2, 35.14, 35.51 and 35.57. The regulatory use of the term authorized medical physicist includes only medical physicists for the following medical uses: Strontium-90 (Sr-90) eye applicators, remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery (Gamma Knife®) units. Therefore, this RIS applies only to licensees with these devices. No specific action nor written response is required.

BACKGROUND

On March 30, 2005, the Commission published a final rule, in the *Federal Register*, amending specific sections in 10 CFR Part 35 (70 FR 19336). The rule revised regulations for the recognition of specialty boards, whose certification processes can demonstrate the training and experience of individuals for serving as radiation safety officers, authorized nuclear pharmacists, AMPs, or authorized users. The rule also included additional revisions to other training and attestation requirements for these individuals. Subpart J, of prior 10 CFR Part 35 (Training and Experience Requirements), remained in effect for a transition period, and expired on October 25, 2005. Agreement States have until April 29, 2008, three years from the effective date of the final rule, to establish regulations compatible with the revised rule.

All specialty boards listed in former 10 CFR Part 35, Subpart J, were contacted about application for NRC recognition of one or more of their certification processes, under the boards' recognition requirements, in the revised training and experience sections of Part 35, Subparts B, and D through H. Each specialty board was requested to supply NRC with an effective date for when its certification process met, or would meet, the revised training and experience requirements in 10 CFR Part 35. The procedures for NRC recognition of board certifications and the recognized certification processes, with the associated effective dates, are listed on NRC's medical-use tool kit web site under "Other Guidance" at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

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The revised Part 35 offers four methods for individuals seeking to be recognized as AMPs at NRC licensed medical-use facilities. The regulations in 10 CFR 35.51 specify two of these methods: (1) Approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience, referred to as the "certification pathway"; or (2) Approval by NRC, an NRC master materials licensee (MML), an NRC broad-scope medical-use licensee, or an MML broad-scope medical-use permittee, based on an evaluation of an individual's training and experience, against the requirements described in 10 CFR 35.51(b), referred to as the "alternate pathway."

The third method is described in the provisions of 10 CFR 35.57. Under this section, teletherapy or medical physicists identified on existing Commission or Agreement State licenses or permits before October 24, 2002, or AMPs identified on Commission or Agreement State licenses or permits between October 24, 2002, and April 29, 2005, are exempt from the requirements in 10 CFR 35.51. The intent of 10 CFR 35.57 is to "grandfather" those individuals named on existing Commission or Agreement State licenses or permits, so that they may continue functioning as AMPs for those uses for which they have been previously approved.

The fourth method is implemented through the definition of an AMP in 10 CFR 35.2 and 10 CFR 35.14, medical physicists who are listed as AMPs or teletherapy physicists on Commission or Agreement State medical-use licenses or permits may work as AMPs without the licensee needing to apply for a license amendment. The limited-specific medical-use licensee or permittee only has to notify the NRC or the NRC MML that the individual is working as an AMP, and provide documentation required in 10 CFR 35.14. Some Agreement States have not adopted the notification provisions in 10 CFR 35.14. Accordingly, this method may not be available to medical physicists moving to a new licensee in a particular Agreement State.

There are approximately 109 Gamma Knife® units, 765 remote afterloader units, 12 teletherapy units, and 100 Sr-90 eye applicators licensed in the U.S. NRC licenses about 260 of these devices, and approximately 725 devices are licensed by Agreement States.

SUMMARY OF ISSUE

For many years, NRC has listed medical physicists on licenses for remote afterloader units, teletherapy units, Sr-90 eye applicators, and Gamma Knife® units. In the 2002 revision of 10 CFR Part 35, NRC began identifying these medical physicists as AMPs. However, not all the Agreement States list medical physicists on medical-use licenses. Based on a recent NRC survey, 28 of the 34 Agreement States indicated that they have been or are now listing AMPs on their limited-specific medical-use licenses. The remaining six States indicated they did not previously list AMPs on their licenses, but they will list them by the April 29, 2008, deadline for establishing regulations compatible with the revised rule.

A medical physicist moving from an Agreement State to an NRC licensed medical facility, who was named on a Commission or Agreement State medical-use license or permit that was valid on April 29, 2005, is eligible to use the grandfather provision, in 10 CFR 35.57, to be named as an AMP on the new facility's NRC license. If the medical physicist is listed as a teletherapy physicist, medical physicist, or AMP on an Agreement State license issued subsequent to

April 29, 2005, the new NRC licensed medical facility can permit the individual to work as an AMP under the provisions of 10 CFR 35.2 and 35.14.

Medical physicists for whom the grandfather provisions do not apply, but who are professionally active in Agreement States that do not list medical physicists on their limited-specific medical-use licenses, must apply by either the board certification pathway or the alternate pathway, described in 10 CFR Part 35.51, when seeking AMP recognition on an NRC license or a license in another Agreement State. A board certified medical physicist may not be able to use the board certification pathway to obtain recognition as an AMP if his or her certification board and certification year are not listed on NRC's web site. Furthermore, medical physicists applying for recognition as AMPs by either the board certification pathway or the alternate pathway are subject to the recentness-of-training provisions in 10 CFR 35.59.

Therefore, a medical physicist to whom the grandfather provisions and the notification provisions do not apply and who is practicing in an Agreement State licensed limited-specific medical-use facility is strongly encouraged to request being identified as an AMP listed on the Agreement State license for his or her present facility if the medical physicist may in the future seek to be listed as an AMP on an NRC license or on a license in another Agreement State. Once listed on an Agreement State license, the medical physicist can seek recognized status via the notification provisions described in 10 CFR 35.2 and 10 CFR 35.14, or equivalent regulations in the particular Agreement State.

Even if an Agreement State does not identify teletherapy physicists, medical physicists, or AMPs on limited-specific medical-use licenses, a medical physicist located at a broad-scope medical-use facility licensed in such an Agreement State is encouraged to have the licensee name the physicist on a permit. This will enable the medical physicist to use the notification provisions described in 10 CFR 35.2 and 10 CFR 35.14, if he or she seeks to be listed as an AMP on an NRC license, or a license in another Agreement State.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

CONTACT

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/

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Enclosure: "List of Recently Issued NMSS
Generic Communications"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555

December 13, 2006

NRC REGULATORY ISSUE SUMMARY 2006-27 AVAILABILITY OF NRC 313A SERIES OF FORMS AND GUIDANCE FOR THEIR COMPLETION

ADDRESSEES

All NRC medical-use licensees, commercial nuclear pharmacies, and U.S. Nuclear Regulatory Commission (NRC) Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

INTENT

NRC is issuing this Regulatory Issue Summary (RIS) to inform addressees of the availability of the NRC 313A series of forms and the guidance for the completion of these forms. No specific action or written response is required. NRC is providing this RIS to the Agreement States for their information and for distribution to their medical licensees as appropriate.

BACKGROUND

A person wishing to be licensed to possess, use, or distribute licensed material must submit an application that will permit NRC to determine whether the applicant has training, experience, equipment, facilities, and procedures, for the use of radioactive material, that are adequate to protect the public health and safety. NRC Form 313, "Application for Material License," which may also include the NRC Form 313A series of forms, for medical use and commercial nuclear-pharmacy applicants, is used to provide the information required. The information provided in the NRC Form 313A series of forms permits NRC to determine whether the applicant has training and experience, for the medical or commercial nuclear-pharmacy uses of radioactive material, that are adequate to protect the public health and safety.

SUMMARY OF ISSUE

This RIS addresses the revision of the single NRC Form 313A used by medical Radiation Safety Officers, medical physicists, nuclear pharmacists, and nine different types of physicians, into six distinct new NRC Form 313As, with the following titles:

> NRC FORM 313A(RSO), "RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]";
>
> NRC FORM 313A(AMP), "AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]";

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NRC FORM 313A(ANP), "AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]";

NRC FORM 313A(AUD), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]";

NRC FORM 313A(AUT), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"; and

NRC FORM 313A(AUS), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]."

NRC Form 313 must be submitted by all applicants seeking a license for the use of byproduct material. The new NRC Form 313A series of forms may be used by medical use applicants to document training and experience and preceptor attestations for individuals seeking recognition as a Radiation Safety Officer (RSO); Authorized Medical Physicist (AMP); Authorized Nuclear Pharmacist (ANP); or Authorized User (AU). The information required to complete the forms is unchanged from the information required for the old NRC Form 313A and is aligned with the requirements in the 2005 revision of 10 CFR Part 35.

Medical use applicants may elect to use the appropriate form from the NRC Form 313A series, for each new individual, the first time that individual is seeking to be identified as an RSO, AMP, ANP, or AU, or when one of these individuals is seeking to be identified for a new authorization on a limited specific medical license. Broad-scope medical use applicants may use the NRC Form 313A(RSO), when requesting an individual be identified as a new RSO or when adding an additional RSO authorization for the individual. Commercial nuclear-pharmacy applicants may also use NRC Form 313A(ANP) when requesting an individual be identified for the first time as an ANP.

Revised guidance is also attached to aid applicants in completing the six forms in the NRC Form 313A series. The new guidance should facilitate the use of the new forms during new license applications, license amendments, and renewals.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational, and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

Congressional Review Act, 5 U.S.C.§§ 801-80B.

PAPERWORK REDUCTION ACT STATEMENT

This Regulatory Issue Summary contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval number 3150-0120, which expires October 31, 2008.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

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Enclosures:
1. List of Recently Issued FSME/NMSS Generic Communications
2. Licensing Guidance for Using the NRC FORM 313A Series of Forms
3. NRC Form 313A(RSO), "RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]"
4. NRC FORM 313A(AMP), "AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]"
5. NRC FORM 313A(ANP), "AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]"
6. NRC FORM 313A(AUD), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"
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